

Clinical Policy: Emicizumab-kxwh (Hemlibra)

Reference Number: CP.PHAR.370

Effective Date: 01.16.18

Last Review Date: 02.18

[Revision Log](#)

Line of Business: Medicaid, HIM-Medical Benefit

See [Important Reminder](#) at the end of this policy for important regulatory and legal information.

Description

Emicizumab-kxwh (Hemlibra[®]) is a bispecific factor IXa- and factor X-directed antibody.

FDA Approved Indication(s)

Hemlibra is indicated for routine prophylaxis to prevent or reduce the frequency of bleeding episodes in adult and pediatric patients with hemophilia A (congenital factor VIII deficiency) with factor VIII inhibitors.

Policy/Criteria

Provider must submit documentation (including such as office chart notes, lab results or other clinical information) supporting that member has met all approval criteria.

It is the policy of health plans affiliated with Centene Corporation[®] that Hemlibra is **medically necessary** when the following criteria are met:

I. Initial Approval Criteria

A. Congenital Hemophilia A with Inhibitors (must meet all):

1. Prescribed for routine prophylaxis of bleeding episodes in patients with congenital hemophilia A (factor VIII deficiency);
2. Patient has inhibitors (antibodies) to factor VIII;
3. Prescribed by or in consultation with a hematologist;
4. Dose does not exceed 3 mg/kg weekly during the first four weeks of therapy, or 1.5 mg/kg weekly thereafter.

Approval duration: 6 months

B. Other diagnoses/indications

1. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized): HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid.

II. Continued Therapy

A. Congenital Hemophilia A with Inhibitors (must meet all):

1. Currently receiving medication via Centene benefit or member has previously met initial approval criteria;
2. Documentation of continued presence of inhibitors to factor VIII;
3. Member is responding positively to therapy;

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4. If request is for a dose increase, new dose does not exceed 3 mg/kg weekly during the first four weeks of therapy, or 1.5 mg/kg weekly thereafter.

Approval duration: 6 months

B. Other diagnoses/indications (must meet 1 or 2):

1. Currently receiving medication via Centene benefit and documentation supports positive response to therapy.
Approval duration: Duration of request or 6 months (whichever is less); or
2. Refer to the off-label use policy for the relevant line of business if diagnosis is NOT specifically listed under section III (Diagnoses/Indications for which coverage is NOT authorized: HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid).

III. Diagnoses/Indications for which coverage is NOT authorized:

- A. Non-FDA approved indications, which are not addressed in this policy, unless there is sufficient documentation of efficacy and safety according to the off label use policies – HIM.PHAR.21 for health insurance marketplace and CP.PMN.53 for Medicaid or evidence of coverage documents.

IV. Appendices/General Information

Appendix A: Abbreviation/Acronym Key

FDA: Food and Drug Administration

Appendix B: Therapeutic Alternatives

Not applicable

Appendix C: General Information

- The elimination half-life of Hemlibra is 27.8 ± 8.1 days. Therefore, the “on-demand” use of Hemlibra for the treatment of acute bleeding episodes is inappropriate.
- There is insufficient data to support the use of Hemlibra for the treatment of hemophilia B either with or without inhibitors.
- A black box warning exists for Hemlibra regarding the potential for thrombotic microangiopathy and thrombotic events when used concurrently with Feiba > 100 U/kg/day for 24 hours or more. Additional monitoring is recommended with concomitant use of the two agents. Discontinuation of Feiba and suspended dosing of Hemlibra is recommended if symptoms occur.

V. Dosage and Administration

Indication	Dosing Regimen	Maximum Dose
Routine prophylaxis of bleeding episodes	3 mg/kg SC weekly for four weeks, followed by 1.5 mg/kg SC weekly thereafter	3 mg/kg weekly

VI. Product Availability

Single-dose vials for injection: 30 mg/mL, 60 mg/0.4 mL, 105 mg/0.7 mL, 150 mg/mL

VII. References

1. Hemlibra Prescribing Information. South San Francisco, CA: Genentech, Inc.; November 2017. Available at https://www.gene.com/download/pdf/hemlibra_prescribing.pdf. Accessed December 20, 2017.

Reviews, Revisions, and Approvals	Date	P&T Approval Date
Policy created	01.16.18	02.18

Important Reminder

This clinical policy has been developed by appropriately experienced and licensed health care professionals based on a review and consideration of currently available generally accepted standards of medical practice; peer-reviewed medical literature; government agency/program approval status; evidence-based guidelines and positions of leading national health professional organizations; views of physicians practicing in relevant clinical areas affected by this clinical policy; and other available clinical information. The Health Plan makes no representations and accepts no liability with respect to the content of any external information used or relied upon in developing this clinical policy. This clinical policy is consistent with standards of medical practice current at the time that this clinical policy was approved. “Health Plan” means a health plan that has adopted this clinical policy and that is operated or administered, in whole or in part, by Centene Management Company, LLC, or any of such health plan’s affiliates, as applicable.

The purpose of this clinical policy is to provide a guide to medical necessity, which is a component of the guidelines used to assist in making coverage decisions and administering benefits. It does not constitute a contract or guarantee regarding payment or results. Coverage decisions and the administration of benefits are subject to all terms, conditions, exclusions and limitations of the coverage documents (e.g., evidence of coverage, certificate of coverage, policy, contract of insurance, etc.), as well as to state and federal requirements and applicable Health Plan-level administrative policies and procedures.

This clinical policy is effective as of the date determined by the Health Plan. The date of posting may not be the effective date of this clinical policy. This clinical policy may be subject to applicable legal and regulatory requirements relating to provider notification. If there is a discrepancy between the effective date of this clinical policy and any applicable legal or regulatory requirement, the requirements of law and regulation shall govern. The Health Plan retains the right to change, amend or withdraw this clinical policy, and additional clinical policies may be developed and adopted as needed, at any time.

This clinical policy does not constitute medical advice, medical treatment or medical care. It is not intended to dictate to providers how to practice medicine. Providers are expected to exercise professional medical judgment in providing the most appropriate care, and are solely responsible for the medical advice and treatment of members. This clinical policy is not intended to recommend treatment for members. Members should consult with their treating physician in connection with diagnosis and treatment decisions.

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Providers referred to in this clinical policy are independent contractors who exercise independent judgment and over whom the Health Plan has no control or right of control. Providers are not agents or employees of the Health Plan.

This clinical policy is the property of the Health Plan. Unauthorized copying, use, and distribution of this clinical policy or any information contained herein are strictly prohibited. Providers, members and their representatives are bound to the terms and conditions expressed herein through the terms of their contracts. Where no such contract exists, providers, members and their representatives agree to be bound by such terms and conditions by providing services to members and/or submitting claims for payment for such services.

Note: For Medicaid members, when state Medicaid coverage provisions conflict with the coverage provisions in this clinical policy, state Medicaid coverage provisions take precedence. Please refer to the state Medicaid manual for any coverage provisions pertaining to this clinical policy.

For Health Insurance Marketplace members, when applicable, this policy applies only when the prescribed agent is on your health plan approved formulary. Request for non-formulary drugs must be reviewed using the formulary exception policy.

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